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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

INTERNATIONAL BROTHERHOOD OF TEAMSTERS LOCAL 456 HEALTH AND WELFARE TRUST FUND and UFCW LOCAL 1776 AND PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, on behalf of themselves and all others similarly situated, Plaintiffs, v. QUEST DIAGNOSTICS INCORPORATED and NICHOLS INSTITUTE DIAGNOSTICS Defendants.	No. 10-cv-01692-RJD-RLM

DEFENDANTS' REPLY MEMORANDUM
IN SUPPORT OF THEIR MOTION TO DISMISS

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I. NO CLAIM HAS BEEN PROPERLY PLEADED AGAINST QUEST DIAGNOSTICS

Plaintiffs cannot hide from their own already amended pleadings. As noted in Defendants' opening brief, to survive a motion to dismiss under modern pleadings rules, mere conclusory allegations do not suffice; rather, the complaint, especially after amendment, "must contain sufficient factual matter" to state a plausible claim for relief. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009), quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 557, 570 (2007) (emphasis supplied).

The "facts" upon which the amended complaint rests are set forth at paragraphs 28-62. Those facts all relate to defendant NID. Not a single fact is asserted against Quest Diagnostics showing it had any role whatsoever in the manufacture or sale of any allegedly defective kits.[1]

In their opposition memorandum, plaintiffs do not, because they cannot, dispute this self-evident point revealed by their own amended pleading. Instead, plaintiffs point to the conclusory paragraphs of their pleading (*see, e.g.*, FAC ¶¶76-85) that simply lump the "Defendants" together in "'naked assertion(s)' devoid of further factual enhancement" and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, [that] do not suffice" to state a claim. *Id.* Such pleading fails for two reasons. First, its total failure to assert any facts

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[1] Thus, the allegations of the First Amended Complaint focus exclusively on NID: "A. The Nichols PHT Kits. Nichols manufactured and sold . . . Kits. Nichols' Kits were sold principally to clinical laboratories . . ." (FAC. ¶28). "Among the kits manufactured, marketed and sold by Nichols were [named products], which were Nichols' lead products. . . ." (¶29). "C. Nichols Immunoassay Kits for Measuring Levels of PTH. In or about 1987, Nichols developed and launched . . . the IRMA Kit " (¶37). "[M]arket pressure led Nichols to develop an automated instrument-based PTH test In 1992 Nichols obtained FDA approval for its Advantage i PTH Kit" (¶41). "The marketing materials that Nichols distributed. . . . " (¶43). " D. The Upward Shift of the Nichols Advantage PTH Kit. Rather than inform doctors about (a) problems [with the kits], in May 2001, Nichols instead notified its customers [of certain adjustments]" (¶45). "E. Nichols' Fraudulent Marketing of PTH Kits. Notwithstanding the claims in Nichols' directional inserts and marketing materials . . . Nichols was aware of defects in the kits. . . . Nonetheless, Nichols continued to indicate in its directional inserts and marketing materials that the [kits were functioning properly]" (¶47). "In 2001, Nichols introduced a new automated PTH test . . . Nichols called this new test the Bio-Intact PTH. Nichols represented [certain correlations regarding tests run on the kits]." (¶50) "F. Nichols' Fraudulent Marketing of the Advantage Diagnostic Kits. In addition to its PTH Kits . . . Nichols manufactured, marketed and sold the following kits [named kits]." . . . (¶52). ". . . Nichols manufactured, marketed and sold 25 OH-D kits that were materially inaccurate and unreliable" (¶53). ". . . Nichols manufactured, marketed and sold ACTH Kits that were materially inaccurate and unreliable" (¶54). ". . . Nichols manufactured, marketed and sold DHTA-S Kits that were materially inaccurate and unreliable." (¶56). See also ¶24: "Nichols manufactured, marketed and sold Kits. . . .

with respect to Quest Diagnostics, as opposed to NID, fails to meet the Supreme Court's tests as recently laid out in *Iqbal* and *Twombly*. This Court has routinely (and recently) dismissed cases against a corporate parent in which, as here, the plaintiff failed to allege how the parent was involved in a subsidiary's alleged wrongdoing. *See, e.g.*, *Parejas v. Gen. Elec. Capital Servs., Inc.*, No. 10-CV-3348, 2011 WL 2635778, at *2 (E.D.N.Y. July 5, 2011) (dismissing plaintiff's Truth in Lending claim against the parent corporation of the subsidiary that held his mortgage, where no facts were alleged against the parent). Second, even if conclusory pleading were still acceptable, which it is not, simply making undifferentiated allegations concerning "Defendants" has never been acceptable under Fed. R. Civ. P. 8. Quest Diagnostics is entitled to "fair notice of what the … claim is and the grounds upon which it rests." *Boykin v. KeyCorp*, 521 F.3d 202, 214 (2d Cir. 2008) (quoting *Twombly*, 550 U.S. at 555). Rule 8 is not satisfied when, as here, a plaintiff merely refers to multiple defendants collectively, without specifying how any individual defendant is alleged to be involved.[2]

Further, plaintiffs' references to a *qui tam* action filed against Quest Diagnostics and NID are both improper and insufficient. Because "unproved allegations of misconduct are not proof of anything," courts (including this Court) "have stricken allegations in complaints referring to investigations of allegations of wrongdoing, even when conducted by governmental agencies." *Dent v. U.S. Tennis Ass'n, Inc.*, No. CV-08-1533, 2008 WL 2483288, at *3 (E.D.N.Y. June 17, 2008). Similarly, plaintiffs cannot use Quest Diagnostics' *qui tam* settlement, in which no admission was made, to meet their pleading requirements in this case to allege wrongdoing by Quest Diagnostics. *Footbridge Ltd. v. Countrywide Home Loans, Inc.*, No. 09 Civ. 4050, 2010

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[2] *Medina v. Bauer*, No. 02 Civ. 8837, 2004 WL 136636, at *6 (S.D.N.Y. Jan. 27, 2004) ("By lumping all the defendants together and failing to distinguish their conduct, plaintiff's amended complaint fails to satisfy the requirements of Rule 8. Specifically, the allegations fail to give adequate notice to these defendants as to what they did wrong."); *see also Appalachian Enters., Inc. v. ePayment Solutions, Ltd.*, 01-CV-11502 , 2004 WL 2831312, at *7, 9 (S.D.N.Y. Dec. 8, 2004) (dismissing a complaint for failing to meet even Rule 8's requirements because it did not "identify any particular defendant that committed any specific act of wrongdoing" and "simply attribute[d] the wrongful acts as being committed collectively").

WL 3790810, at *5 (S.D.N.Y. Sept. 28, 2010) (striking from a complaint allegations based on "pleadings, settlements, and government investigations in other cases").

Finally, while plaintiffs seek to explain away their pleading deficiencies by complaining of a "rather complex" relationship between Quest Diagnostics and NID that is "the subject of outstanding discovery." (Pl. Br. 7-8, nn.5 & 6), as a matter of law they cannot "excuse [their] pleadings based on difficulties [they] encounter[] as a result of the Defendants' alleged convoluted structure of their business practices and plans." *Appalachian Enters.*, 2004 WL 2831312, at *7. Either Quest manufactured the kits or it did not. Either Quest Diagnostics issued misrepresentations about the kits or it did not. This matter has nothing whatsoever to do with the corporate dealings between the entities, and plaintiffs' failure to assert a single fact showing Quest Diagnostics had any role in the manufacture or sale of the kits ends the inquiry. *Id.* at *8. Further, plaintiffs' grumbling footnotes concerning outstanding discovery only demonstrate that they have the process precisely backward. Plaintiffs need to satisfy Fed. R. Civ. P. 9(b) *before* the discovery floodgates are opened; they may not use discovery to meet that burden. *See, e.g.*, *Segal v. Gordon*, 467 F.2d 602, 607-08 (2d Cir. 1972).

II. PLAINTIFFS HAVE FAILED TO ADEQUATELY PLEAD A RICO VIOLATION

A. No Distinct Enterprise Is Alleged

As established in *Defendants' Memorandum*, the distinction between "person" and "enterprise" demanded by RICO 18 U.S.C. § 1962(c) cannot be satisfied by alleging that a corporate parent and its subsidiary somehow infiltrated themselves simply by conducting their regular business to achieve a common corporate purpose through an alleged pattern of racketeering. *Defendants' Memorandum* at p. 6. Plaintiffs do not dispute this settled law. Their two proffered arguments as to why this law does not preempt their incurably flawed RICO theory are without merit.

First, plaintiffs attempt analogy to a case in which what they mischaracterize as two "sibling corporations" were permissibly cast as both defendant "persons" and the infiltrated "enterprise" under RICO § 1962(c). *Plaintiffs' Memorandum* at 9, citing *Securitron Magnalock Corp. v. Schnabolk*, 65 F.3d 256 (2d Cir. 1995). This analysis is misguided precisely because, as the Second Circuit Court of Appeals emphasized, the two corporations in fact were "entirely distinct" from each other, were engaged in two "distinct lines of business," and were related only to the extent that another "distinct" individual (who, significantly, was also alleged as part of the enterprise) had *once* been the principal owner of each company. *Id.* at 263. Here, of course, there is no such separation alleged — plaintiffs' entire theory is premised on Quest Diagnostics, as parent, allegedly "enabl[ing]" NID, its wholly-owned subsidiary, "to routinely conduct" the business of making and selling kits through alleged fraud. *FAC* at ¶¶ 76, 84. In such circumstances of complete corporate overlap, both the *Securitron* panel, and every pertinent Second Circuit case decided *after Securitron*, have recognized that the requisite distinction between person and enterprise cannot be established. *See, e.g., Defendants' Memorandum* at pp. 6-7 and cases cited therein.

Second, Plaintiffs refer in their Memorandum (and not in any pleading) to the possible existence of an array of alleged agents ("marketing firms, physicians, scientists, public relations firms and other consultants"), and argue that, because these "as yet unknown" agents may someday be proven to exist and to be "independent third parties," their inclusion now has infused the alleged enterprise with sufficient distinctiveness to evade dismissal. *Plaintiffs' Memorandum* at pp. 10-11. This argument — even assuming such independence — cannot rescue Plaintiffs' RICO theory. This surmise is made out of whole cloth. Plaintiffs have not pleaded the actual existence of any such third parties, nor do they allege any facts demonstrating that such hypothetical parties did anything whatsoever that was improper or beyond assisting defendants to operate their "routinely conducted" business. *FAC* at ¶84. Courts in this Circuit and others

consistently have held that salting an alleged RICO enterprise with such "agents" — whether "independent" or affiliated — cannot save an otherwise deficient person/enterprise formulation.[3]

B. Failure to Plead a RICO Claim with Particularity

Plaintiffs, at page 12 of their brief, assert that they are relieved of the requirements of Rule 9(b) in pleading their RICO claim because they have provided a description of the underlying scheme and its connection to the mail or wire communications. However, even under that reasoning, plaintiffs were still obligated to plead with adequate particularity each defendant's specific involvement in the alleged underlying fraud and the direction of the alleged enterprise's affairs. *See, e.g.*, *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2nd Cir. 1993); *DiVittorio v. Equidyne Extractive Indus., Inc.*, 822 F.2d 1242, 1247 (2d Cir. 1987); *In re Sumitomo Copper. Litig.*, 995 F.Supp. 451, 454 (S.D.N.Y. 1998). As shown above, plaintiffs have failed to assert with any particularity whatsoever any role by Quest Diagnostics in the manufacture, marketing or sale of the allegedly defective kits.

III. PLAINTIFFS' CLAIMS ARE BARRED BY THE STATUTE OF LIMITATIONS

A. Plaintiffs Were On Inquiry Notice of Their Claims in 2005

Plaintiffs' arguments regarding dismissal on statute of limitations grounds are make-weight and unavailing. First, plaintiffs assert that (i) the recall notices sent to the purported class members in 2005, (ii) the 2005 product hold notice for all of NID's products, (iii) the 2005 FDA Enforcement Bulletins, and (iv) the numerous 2004 and 2005 SEC filings regarding the DOJ's

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[3] *See, e.g., Discon, Inc. v. NYNEX Corp.*, 93 F.3d 1055, 1064 (2d Cir. 1996) ("Discon's reference to unnamed 'attorneys, accountants and other agents' as part of the enterprise does not alter this analysis."); *Riverwoods Chappaqua Corp. v. Marine Midland Bank,* 30 F.3d 339, 344 (2d Cir. 1994) (RICO enterprise cannot consist merely of the corporate defendants and its agents carrying on the regular affairs of the defendants); *In re Parmalat Sec. Litig.*, 479 F. Supp. 2d 332, 346-47 (S.D.N.Y. 2007) ("[T]he Bank's inclusion of 'affiliates and subsidiaries located around the world,' 'culpable employees, directors and officers,' and Parmalat's counsel Zini do not distinguish the enterprise from the person. Nor does the reference to the 'variety of third-party entities' change anything."), and other cases cited in *Defendants' Memorandum* at p. 8 and n.3. The cases relied upon by plaintiff at page 11 of their brief are inapposite. In *In re Actiq Sales and Marketing Practices Litig.*, No. 07-CV-4492 (E.D. Penn. 2009) and *In re Neurontin*, 433 F.Supp. 2d 172 (D.Mass. 2006), the courts found that the manufacturers had bribed third parties to mislead or funnel payments to prescribing physicians. No such allegations are made here. In *In re Zyprexa Products Liability Litig.*, 493 F.Supp. 2d 571 (E.D.N.Y. 2007), the court was not asked to and did not rule on this issue.

criminal investigation of the kits, are being offered to prove the truth of their contents, as opposed to what they contain, so that dismissal is inappropriate. This is plainly wrong. The issue on this motion, which plaintiffs themselves concede, is simply whether these documents put Plaintiffs on inquiry notice. Accordingly, Defendants are not asking the Court to determine any factual issues regarding the documents; they only seek to have the documents considered for "what" they contain, and not their "truth."[4]

Plaintiffs next contend that there is a "factual" issue whether Defendants "concealed" information regarding the kits, which "issue" similarly precludes dismissal. Again, plaintiffs are simply wrong. Plaintiffs do not dispute that the documents which Defendants ask the Court to consider were in fact sent to the members of the putative class or were public information. Thus, plaintiffs concede that the information contained in these documents was not concealed. Accordingly, there is no factual issue of "concealment" to be decided, as Defendants only ask this Court to determine whether inquiry notice was established based on the very documents plaintiffs concede were sent to the laboratories or were otherwise publicly disclosed.[5]

Third, plaintiffs argue they were not put on inquiry notice. This is easily disposed of. The settled law was cited in Defendants' original brief and is not disputed by plaintiffs: once a plaintiff knows that a supplier has delivered defective products inconsistent with prior representations made as to their quality, the plaintiff is on inquiry notice and the limitations period begins to run. *See, e.g., Long Island Lighting Co. v. Imo Indus., Ind.* 6 F.3d 876, 887 (2d

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[4] As noted in Defendants' original memorandum at 15, the issue of whether a plaintiff was placed on inquiry notice is analyzed under an objective standard that can be resolved as a matter of law. *See, e.g., Staehr v. Hartford Fin. Servs. Group, Inc.,* 547 F.3d 406, 427 (2d Cir. 2008).

[5] Plaintiffs make the astounding contention that while the recall notices were undisputedly sent to the laboratories, they were not also sent "to third party payors who also make up the putative class." Plaintiffs' brief, at 21, n..24. Plaintiffs need to re-read their amended complaint, at ¶64, which defines the putative class as "all entities in the United States and its territories, who, for purposes other than resale, purchased, reimbursed and/or paid for . . . the "defective Nichols kits. . . ." Because (as Plaintiffs concede) the kits were sold to clinical laboratories (FAC at ¶28), and because "third party payors" such as plaintiffs only reimburse for tests performed on the kits and not the kits themselves, whether or not the recall notices were sent to third party payors is simply irrelevant to the statute of limitations issue. Further, this argument ignores the FDA Bulletins and the SEC filings, which were public documents.

Cir. 1993). Accordingly, the fact that the initial recall notices and FDA Enforcement Bulletins referred to specific lots of defective kits, as opposed to identifying every single kit, is immaterial.[6] In any event, the initial recalls were soon followed by a total hold on all NID products on June 16, 2005. Plaintiffs cavil that even then they weren't on notice because that recall suggested that the defects would be "corrected shortly." But this fact only further dooms this action. The "problems" were never corrected, and 2005 passed into 2006. The failure to "correct" the problem by April 14, 2006, almost a year later, only more strongly demonstrates that plaintiffs were on inquiry notice by that time. And even more powerfully, not only did Plaintiffs know that NID had failed to "correct" the "problem" "shortly," they were repeatedly told by SEC filings that in fact the Department of Justice had commenced a criminal investigation regarding the manufacture of the kits. Further, the public was also notified by these filings that qui tam actions may be pending and that NID could well face criminal and civil damages, fines and penalties as a result of the DOJ investigation and third party claims regarding the kits. For Plaintiffs to suggest that this constellation of public documents and information did not, as an objective fact, put them on inquiry notice, is wholly disingenuous.

Plaintiffs' effort to invoke "equitable tolling" is unavailing for two reasons. First, as noted, this motion to dismiss is based on the recall notices, FDA Enforcement Bulletins, the total hold notice and the SEC filings, all of which plaintiffs concede were sent to the laboratories or otherwise in the public record. Thus, these matters by definition were not "concealed," and if, as is apparent, they were sufficient to put plaintiffs on inquiry notice, then dismissal is warranted as a matter of law. Second, as plaintiffs concede in their Memorandum at 24, equitable tolling requires the plaintiffs to have exercised due diligence. Plaintiffs have alleged no diligence of any kind at any time, and certainly not before April 15, 2009. The very case cited by plaintiffs

[6] *See, e.g., Salinger v. Projectavision, Inc.*,. 934 F.Supp. 1402, 1408-09 (S.D.N.Y.1996) ("The Plaintiffs need not be able to learn the precise details of the fraud, but they must be capable of perceiving the general fraudulent scheme based on the information available to them. . . . The statute is not tolled for a plaintiff's leisurely discovery of the full details of the alleged schemes. Instead, the period runs from the time at which a plaintiff should have discovered the general fraudulent scheme.")

themselves makes this clear. *See Allstate Insurance Co. v. Valley Physical Med. & Rehab. P.C.*, 475 F.Supp.2d 213, 232 (E.D. N.Y. 2007) (equitable tolling did not apply because of plaintiff's lack of diligence).[7]

Plaintiffs do not respond to Defendants' arguments that their state law claims are also time-barred. Nor does equitable tolling save those claims. As discussed fully in Defendants' Memorandum at pages 19-21, equitable tolling can never apply to breach of warranty or unjust enrichment claims, and in any event for the reasons stated above equitable tolling is inapplicable here to any claims.

IV. PLAINTIFFS HAVE FAILED TO ALLEGE ANY VALID STATE LAW CLAIMS

Plaintiffs' state law claims may be addressed seriatim:

Third Case of Action – Consumer Protection Laws: Plaintiffs are allegedly residents of New York and Pennsylvania. Accordingly, it is only the consumer protection laws of those states that are relevant.[8] Under New York law, third party payors such as plaintiffs cannot bring an action under General Business Law § 349 since allegations of injury from reimbursing other parties for health care costs is too remote an injury for purposes of §349. *Blue Cross and Blue Shield of New Jersey, Inc. v. Philip Morris USA Inc.*, 3 N.Y.3d 200, 206-07, 818 N.E.2d 1140, 1144-45 (2004). Plaintiffs (mis)cite *In re Zyprexa Prod. Liability Litig.*, 493 F. Supp. 2d 571, 576 (E.D.N.Y. 2007), for the proposition that they have suffered a sufficiently direct injury for purposes of § 349. *Zyprexa* is inapplicable because it involved health plans who were *direct* purchasers of the drug at issue, *id.* at 577, and not health plans that were simply reimbursing

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[7] Plaintiffs cite this case as an example of a decision denying a statute of limitations defense at the motion to dismiss stage based on equitable tolling. In fact, the Court held that the statute of limitations had run and the plaintiff's claims were *not* equitably tolled. *Id.*

[8] Further, even assuming that plaintiffs could maintain an action under the consumer protection statute of the state of their residency, all other state claims must be dismissed. *See, e.g., Gunther v. Capital One, N.A.*, 703 F. Supp. 2d 264, 274-75 (E.D.N.Y. April 8, 2010) (dismissing claims brought under Connecticut consumer protection act because named plaintiff did not reside in Connecticut); *Temple v. Circuit City Stores, Inc.*, Nos. 06-5303, 06-5304, 2007 WL 2790154 *8 (E.D.N.Y. Sept. 25, 2007) (dismissing all consumer protection claims under all state laws other than Tennessee because that is where named plaintiffs resided).

members for certain health care costs, as is the case here and in *Philip Morris*.[9] Pennsylvania's consumer protection law only creates a private cause of action for "[a]ny person who *purchases* or leases goods or services *primarily for personal, family or household purposes* ..." 73 Pa. Cons. Stat. § 201-9.2 (emphasis added). Plaintiffs are not purchasers of the allegedly defective kits, and even if they were, such purchase could not have been "primarily for personal, family or household purposes," because they did not personally have any tests performed on the kits.

Fourth, Fifth and Sixth Causes of Action – Common Law Fraud and Misrepresentation Claims: Plaintiffs concede that they must adequately plead reliance to maintain their fraud and misrepresentation claims. Not surprisingly, because plaintiffs never purchased the kits, they do not allege any facts showing reliance. If plaintiffs had truly relied upon a representation from Nichols or Quest, it would be simple for them to allege what that representation was, and the circumstances surrounding their reliance. They have not done so.

Seventh and Eighth Causes of Action – Breach of Warranty: The cases noted by plaintiffs make it clear that a warranty only extends to *purchasers* in the chain of distribution, and not to entities — such as plaintiffs here — who do not actually purchase the allegedly defective product. While it is the case that in some states downstream purchasers of goods can bring a breach of warranty claim, plaintiffs have cited no authority for the proposition that persons who never purchase the allegedly defective good are covered by the warranty. The elimination of vertical privity in some jurisdictions to allow a purchaser to maintain a claim

[9] As plaintiffs are aware, the *Zyprexa* decision they rely upon was vacated in part by the Second Circuit, *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010), which is yet another reason why any reliance on that decision is misplaced.

against a remote supplier is not an elimination of the requirement that the plaintiff be an actual purchaser in order to bring that claim.[10]

Ninth Cause of Action – Unjust Enrichment: *Sperry v. Crompton Corp.*, 8 N.Y. 204, 863 N.E.2d 1012 (2007), cited by plaintiffs, directly supports Defendants' motion to dismiss. Because plaintiffs simply reimbursed their members for the cost of tests performed on the kits, their connection to Nichols is too attenuated. *Id.* at 215-16 (dismissing unjust enrichment claims brought by purchaser of tires against manufacturers of chemicals used to make tires). The decision in *Sperry* is consistent with decisions by California and New Jersey courts dismissing unjust enrichment claims when the relationship between the plaintiff and defendant is similarly attenuated. *Jane Doe I v. Wal-Mart Stores, Inc.*, No. CV 05-7307, 2007 WL 5975664 *5 (C.D. Cal. Mar. 30, 2007); *Premier Pork L.L.C. v. Westin, Inc.*, C.A. No. 07-1661, 2008 WL 724352 *14-*15 (D.N.J. Mar. 17, 2008).

CONCLUSION

For the reasons stated above and in Defendants' opening brief, it is respectfully submitted that the Motion to Dismiss should be allowed.

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[10] *See Goodman v. PPG Indus., Inc.*, 849 A.2d 1239, 1243 (Penn. Sup. 2004) (third parties may enforce express warranties only where the party issuing the warranty expressly communicates the terms to the third party); *Alloway v. General Marine Indus., L.P.*, 695 A.2d 264, 275 (N.J. 1997) (privity not required for *buyer* to reach up the chain of distribution to manufacturer); *Spring Motors Dist., Inc. v. Ford Motor Co.*, 489 A.2d 660, 674 (N.J. 1985) (allowing an action by a commercial *purchaser* against a remote supplier). Neither does *Kinetic Co. v. Medtronic, Inc.* assist plaintiffs. First, *Kinetic* addresses Minnesota's consumer protection statute. *Kinetic*, 672 F. Supp. 2d 933, 947 (D.Minn. 2009). Second, while the third-party payors in *Kinetic* did not directly purchase the defective medical device from the manufacturer itself, they had paid for the actual devices, which were then implanted in their insureds and later had to be replaced. *Id.* at 940. As such, they remained in the purchasing chain, unlike the plaintiffs in this case, who are not purchasers at all.

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